510(k) SUMMARY

K073024

Submitted by:	Masimo Corporation 40 Parker Irvine, CA 92618 (949) 297-7000 FAX (949) 297-7001
Official Correspondent:	James Cronin, Vice President of Regulatory Affairs
Contact for this Submission:	Marguerite Thomlinson, Manager of Regulatory Affairs
Date Summary Prepared:	October 24, 2007
Trade Name	Masimo Rainbow SET® Rad 87 Pulse CO-Monitor and Accessories,
Common Name	Pulse Oximeter
Classification Name	Oximeter (74DQA) (870.2700) (JKS)
Substantially Equivalent Devices	Masimo SET® Radical 7 Pulse CO-Oximeter and Accessories 510(k) Number – K06120 Masimo Rainbow Adhesive Sensors 510(k) Number – K071024

Description of the Device and Its Intended Use

The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter (Rad 87) with Rainbow technology is noninvasive monitoring of arterial oxygen saturation (%SpO_2), pulse rate, carboxyhemoglobin saturation (%SpCO), and/or methemoglobin saturation (%SpMet). The Rad 87 features an LED display that continuously displays numeric values for %SpO_2 and pulse rate. Other information displayed by the Rad 87 include: %SpCO and/or %SpMet, Low Signal IQ (Low SIQ), Perfusion Index (PI), Pleth Variability Index (PVI), alarm status, alarm silence, battery life, sensor status, trends, and pleth waveform. The Rad 87 has output interfaces including Nurse Call analog output, RS-232 serial output, and optional wireless connection to Patient SafetyNet.

The Rad 87 is intended to be used with the following sensors:

- Masimo LNOP series of oximetery sensors
- Masimo LNCS series of oximetery sensors
- Masimo Rainbow series of (SpCO/SpMet) sensors

The Rad 87 is also intended to be used with the Masimo patient cables, including Red and Rainbow patient cables.

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Configurations

The Masimo SET® Rad 87 Pulse CO-Oximeter comes in four models:

- Horizontal, without optional radio
- Horizontal, with optional radio
- Vertical, without optional radio
- Vertical, with optional radio

Standard and Optional Features

Each of the four models mentioned above includes the following key standard features:

- SpO_2
- Pulse Rate
- Low Signal IQ
- Perfusion Index

The following key optional features are also available for each of these four models:

- SpCO
- SpMet
- Pleth Variability Index

Indications for Use/ Intended Use

The Masimo SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), carboxyhemoglobin saturation (measured by an SpCO/SpMet sensor), and/or methemoglobin saturation (measured by an SpCO/SpMet sensor). The Masimo SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Specifications and Ranges

Range

Oxygen Saturation (%SpO_2)	0 - 100%
Carboxyhemoglobin Saturation (%SpCO)	0 - 99%
Methemoglobin Saturation (%SpMet)	0 - 99.9%
Pulse Rate (bpm)	25 - 240
Perfusion Index	0.02 - 20%
Pleth Variability Index	0 - 100%

Accuracy

Oxygen Saturation (%SpO_2) - During No Motion Conditions

Adults, Pediatrics, Infants, Neonates	60% - 80% ± 3%
Adults, Pediatrics, Infants, Neonates	70% - 100% ± 2%
Adults, Pediatrics, Infants, Neonates	0% - 69% unspecified

Oxygen Saturation (% SpO_2) - During Motion Conditions

Adults, Pediatrics, Infants, Neonates	70% - 100% ± 3%
Adults, Pediatrics, Infants, Neonates	0% - 69% unspecified

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Oxygen Saturation (%SpO_2) - During Low Perfusion Conditions

Adults, Pediatrics, Infants, Neonates	70% - 100% ± 2%
Adults, Pediatrics, Infants, Neonates	0% - 69% unspecified

Carboxyhemoglobin Saturation (% SpCO) 0% - 40% ± 3%

Methemoglobin Saturation (% SpMet) 0% - 15% ± 1%

Pulse Rate (bpm) - During No Motion Conditions

Adults, Pediatric, Neonates 25 - 240 ± 3 bpm

Pulse Rate (bpm) - During Motion Conditions

Adults, Pediatric, Neonates 25 - 240 ± 5 bpm

Pulse Rate (bpm) - During Low Perfusion Conditions

Adults, Pediatric, Neonates 25 to 240 ± 3 bpm

Resolution

Oxygen Saturation (% SpO_2)	1%
Carboxyhemoglobin Saturation (% SpCO), digital display	1%
Methemoglobin Saturation (% SpMet), digital display	0.1%
Pulse Rate (bpm)	1

Interfering Substances

Dyes, or any substance containing dyes, that change usual arterial pigmentation may cause erroneous readings.

SpO_2 is empirically calibrated to functional arterial oxygen saturation in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb). A pulse oximeter can not measure elevated levels of COHb or MetHb. Increases in either COHb or MetHb will affect the accuracy of the SpO_2 measurement.

For increased COHb: COHb levels above normal tend to increase the level of SpO_2. The level of increase is approximately equal to the amount of COHb that is present. NOTE: High levels of COHb may occur with a seemingly normal SpO_2. When elevated levels of COHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be preformed.

For increased MetHb: the SpO_2 may be decreased by levels of MetHb of up to approximately 10% to 15%. At higher levels of MetHb, the SpO_2 may tend to read in the low to mid 80s. When elevated levels of MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be preformed.

Power

AC Power	100 – 240 VAC, 47-63 Hz, 15VA
Rechargeable battery	Sealed lead acid

Environmental

Operating Temperature	41°F to + 104°F (5°C to +40°C)
Storage Temperature	-40°F to + 158°F (-40°C to +70°C)
Relative Humidity	5% to 95% non-condensing
Operating Altitude	500 mbar to 1060 mbar pressure -1,000 ft to 18,000 ft (-304 m to 5,486 m)

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Circuitry
- Microprocessor controlled
- Automatic self-test of oximeter when powered on
- Automatic setting of parameters
- Automatic alarm messages

Display

Type	LED
Data Displayed	SpO2 %, Pulse Rate, % SpCO and/or %SpMet, alarm status, status messages, Signal IQ, perfusion index, pleth variability index, APOD, sensitivity, wireless radio connection, system status light

Audio indicators
- Adjustable volume
- Alarm silence
- Sensor condition alarms
- System failure and battery low alarms

Physical characteristics

Dimensions:	8.2" x 6.0" x 3.0" (20.8cm x 15.2cm x 7.6cm)
Weight:	2.1 lbs (0.908 kg)

Modes

Averaging mode:	2, 4, 8, 10, 12, and 16 seconds
Sensitivity	Normal, Maximum, APOD

Principles of Operation

SpO_2 General Description

Pulse oximetry is a continuous and non-invasive method of measuring the level of arterial oxygen saturation in blood. The measurement is taken by placing a sensor on a patient, usually on the fingertip for adults, and the hand or foot for neonates. The sensor connects to the pulse oximetry instrument with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data in two ways: 1) as a percent value for arterial oxygen saturation (SpO_2), and 2) as a pulse rate (PR).

SpCO and SpMet General Description

Pulse CO-oximetry is a continuous and non-invasive method of measuring the levels of carbon monoxide concentration (SpCO) and oxidized hemoglobin concentration (SpMet) in arterial blood. It relies on the same principles of pulse oximetry to make its SpCO/SpMet measurements. The measurements are taken by placing a sensor on a patient, usually on the fingertip for adults. The sensor connects directly to the pulse CO-oximetry instrument or with a patient cable. The sensor collects signal data from the patient and sends it to the instrument. The instrument displays the calculated data as percentage value for the SpCO and the SpMet. The Rad 87 is a combined SpO_2, SpCO, and/or SpMet monitor with the same setup as that of a pulse oximeter and can display SpO_2 in percentage values, pulse rate in beats per minute, SpCO in percentage values, and/or SpMet in percentage values.

Pulse oximetry is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), and methemoglobin (blood with oxidized hemoglobin content) species differ in their absorption of visible and infrared light.

2. The amount of arterial blood in tissue changes with your pulse (photoplethysography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.

The Rad 87 Pulse CO-Oximeter uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, and blood with oxidized hemoglobin content. Signal data is obtained by passing various visible and infrared lights (LED's, 400 to 1000nm) through a capillary bed (for example, a fingertip, a hand, a foot), and measuring changes in light absorption during the blood pulsatile cycle. The photodetector receives the light, converts it into an electronic signal and sends it to the Rad 87 for calculation.

Once the Rad 87 receives the signal from the sensor, it utilizes Masimo SET signal extraction technology to calculate the patient's functional oxygen saturation, fractional concentrations of carboxyhemoglobin and methemoglobin, and pulse rate. The SpCO and the SpMet measurements rely on multiwavelength calibration equations to estimate the percentages of carboxyhemoglobin and methemoglobin in arterial blood.

Method of Operation

The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter (Rad 87) is turned on. An oximetry sensor is attached to a patient's finger and one end of a patient cable is connected to the sensor and the other end connected to the Rad 87 Pulse CO-Oximeter.

The monitor will begin continuously displaying the patient's pulse rate, and SpO_2 value. If the Rad 87 is configured for SpCO and/or SpMet monitoring and the Rainbow sensor is attached to the patient's finger, then SpCO and/or SpMet values are also continuously displayed. The practitioner can then use the information that is continuously displayed on the monitor to help assess the condition of the patient and as an aide in determining if any intervention is required by the practitioner.

Once the practitioner determines the patient no longer requires monitoring, the cable is disconnected from the sensor, the CO-oximetry sensor is removed (and disposed of if it is a single use device), and the power to the monitor is turned off.

Description of Device Design Requirements

The Rad 87 was designed in accordance to the requirements of the following standards:

- Electrical Safety requirements per BS EN 60601-1
- Performance requirements per ISO 9919

Identification of the Risk Analysis Method

Risk analysis was performed on the Rad 87 in accordance with ISO 14971 for the assessment of both general and specific device's design. The results of the risk analysis are included in this filing.

Discussion of the Device Characteristics

The Rad 87 characteristics include performance that meets or exceeds the requirements of ISO 9919. Additionally, the device is designed to be electrically safe for the patient and the operator in accordance with BS EN 60601-1. Verification and validation tests were completed whenever possible to mitigate risks identified in the device. For inherent risks that cannot be mitigated through product testing, the user will be notified through the product labeling.

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Description of the Performance Aspects

Non-Clinical Tests Performed that Support a Determination of Substantial Equivalence.

The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and Accessories were subjected to bench testing using a simulator that determined the performance accuracy of the instruments against the simulator under the range of oxygen saturation and pulse rates that the device specify.

Clinical Tests Performed that Support a Determination of Substantial Equivalence.

Clinical studies were performed using the Masimo Rainbow SET® Technology on healthy adult volunteer subjects during no motion and motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a laboratory CO-oximeter.

Conclusion

The information in this 510(k) submission demonstrates that the Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 8 2008

Ms. Marguerite Thomlinson
Manager of Regulatory Affairs
Masimo Corporation
40 Parker
Irvine, California 92618

Re: K073024
Trade/Device Name: Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and Accessories
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, JKS
Dated: January 9, 2008
Received: January 10, 2008

Dear Ms. Marguerite Thomlinson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

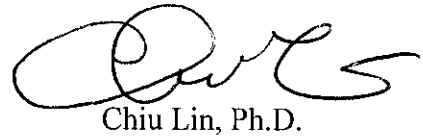
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and Accessories

Indications For Use:

The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate (measured by an SpO_2 sensor), carboxyhemoglobin saturation (measured by an SpCO/SpMet sensor), and/or methemoglobin saturation (measured by an SpCO/SpMet sensor). The Masimo Rainbow SET® Rad 87 Pulse CO-Oximeter and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments.

Prescription Use ____X____ **AND/OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109 Subpart D) (Per 21 CFR 801.109 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K073024

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